DEAV1999/L060 US NP2

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Joachim BRENDEL et al.

Application No.: 10/691,624

Filed: October 24, 2003

For: 2'-SUBSTITUTED 1, 1'-BIPHENYL-2-CARBOXAMIDES, PROCESSES FOR THEIR PREPARATION, THEIR USE AS MEDICAMENTS, AND PHARMACEUTICAL PREPARATIONS COMPRISING THEM

Prior Group Art Unit: 1625

Prior Examiner: R. Desai

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO THE RESTRICTION REQUIREMENT

This paper is in response to the Office Action dated November 24, 2004 ("the Action"), in which a Restriction Requirement was issued in connection with the above-identified patent application. Applicants respectfully request reconsideration of the Restriction Requirement in view of the following remarks.

Filed concurrently herewith is a Petition for Extension of Time pursuant to 37 C.F.R. § 1.136(a) for three (3) months.

The Requirement for Restriction

The Action requires Applicants to select one of the following six groups of allegedly patentably distinct inventions for examination.

I. Claims 1-8, 15-19 in part, drawn to compounds and pharmaceutical compositions wherein R1 is as given in claim 18, wherein all the Rs are non-hetero ring or group containing and R30 and R31 do not form a ring classified in class 564 and various subclasses. A further election of a single species is required.

II. Claims 1-8, 15-19 in part, drawn to compounds and compositions wherein R1 is other than group I and R14 is a hetero group, furyl or thienyl and R30 and R31 do not form a ring classified in class 548, 549 and various subclasses. A further election of a single species is required.

III. Claims 1-8, 15-19 in part, drawn to compounds and compositions wherein R30 and R31 form a ring and there are no other hetero rings or groups in the R's, classified in class 564 and various subclasses. A further election of a single species is required.

IV. Claims 1-8, 15-19 in part, drawn to compounds and compositions wherein R30 and R31 do form a ring and R14 is a hetero ring containing group, classified in class 548, 549 and various subclasses. A further election of a single species is required.

V. Claims 1-8, 15-19 in part, drawn to compounds and compositions wherein R1-R31 are different than those given in the above groups classified in different classes subclasses. A further election of a single species is required.

VI. Claims 9-14, drawn to different methods of treating the various diseases listed, classified in class 514 and various subclasses.

Regarding groups I to V, the Action asserts that each group has "a different core structure and the core is not a contribution over the prior art [h]ence they are patentably distinct" (Action at 3).

Traversal of Restriction Requirement

Applicants' claims include Markush groups. Groups I to V of the restriction requirement are "grouped" largely according to similar members within certain of the Markush groups. The claims of Group VI define methods of treating the various diseases with the compounds defined by the claims of Groups I to V.

Applicants submit respectfully that the Examiner's requirement for restriction (hereinafter "the restriction requirement") is improper in that the restriction requirement is in contravention to Patent Office policy as set forth in MPEP §803.02 and the relevant case law.

Traversal Based on MPEP §803.02 Considerations

Patent Office policy, as set forth in MPEP §803.02, provides that there is no basis for a restriction requirement of a Markush-claimed invention where two factors are met, *i.e.*,

> ... compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.

Applicants' claimed invention meets the aforesaid factors. As detailed below, the claimed compounds not only share a ***common utility***, but also share a ***substantial structural feature*** that is essential to that utility.

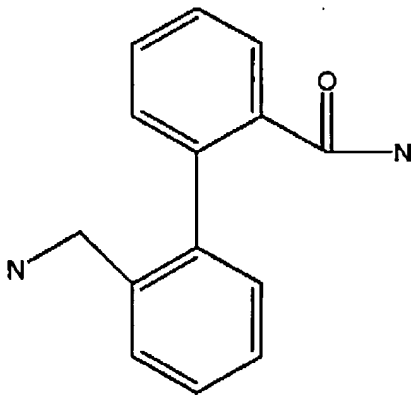
Regarding the first factor, *i.e.*, common utility, the Action does not dispute that all of the claimed compounds share the same utility which is to "act on the so-called Kv1.5 potassium channel and inhibit a potassium current" in the human atrium (see, e.g.,

Applicants' specification at page 2, lines 17 to 19). As such, the claimed compounds are suitable for use as novel antiarrhythmic compounds and, accordingly, are useful in the treatment and/or prophylaxis of diseases such as, for example, atrial fibrillation (id. at lines 19 to 22). Therefore, Applicants' claimed invention meets the first factor.

Regarding the second factor, *i.e.*, substantial structural feature being essential to the utility, the Action apparently alleges that the claimed compounds do not share a substantial structural feature associated with the function of treating the indicated conditions:

> [i]n the instant case the different inventions have a ***different*** core structure and the core structure is not a contribution over the prior art[.] Hence they are patentably distinct

(Action at 3) (emphasis added). This statement, however, is factually incorrect and is internally contradicted by other portions the Action. As detailed below, there indeed ***is*** a substantial structural feature that is common to all of the members of the above-identified groups, namely, the common feature defined by the formula



which is the same structure identified by the Examiner as the core structure for purposes of an alleged prior art search (Action at pages 3 to 4). Thus, by the Action's own admission, the claimed compounds ***have*** a common core structure. Since the

Action has not provided any evidence or technical reasoning to support the position that this shared structural feature is ***not*** essential to the utility of the claimed compounds, there is no reason to doubt that it is. Therefore, Applicants' claimed invention meets the second factor.

The Action also appears to base its conclusion [that more than one invention is represented by Groups I through V] on the allegation that the above-identified core structure itself is not a contribution over the prior art (Action at 3). Without commenting on the merits of this allegation, Applicants submit respectfully that patentability over the prior art is ***not*** a factor to be considered by an Examiner when issuing a restriction requirement. Indeed, to the contrary, the MPEP provides express instruction that there is a ***presumption of patentability*** when considering the question of restriction:

> ***[f]or the purpose of a decision on the question of restriction, and for this purpose only, the claims are ordinarily assumed to be in proper form and patentable*** (novel and unobvious) over the prior art.
>
> This assumption, of course, is not continued after the question of restriction is settled and the question of patentability of the several claims in view of prior art is taken up

(MPEP § 806.02) (emphasis added). Accordingly, consideration of patentability of the core structure over the prior art is clearly improper.

In sum, the two-prong test of MPEP § 803.02 is satisfied by Applicants' claims. The Action does not dispute that all of the claimed compounds share the same utility and the compounds represented by the claims of Groups I to V share a substantial structural feature that is essential to that utility. Significantly, the Action provides no

evidence or technical reasoning to the contrary. Accordingly, the restriction requirement is improper and should be withdrawn.

Traversal Based in Case Law Considerations

As detailed below, well-settled case law such as, for example, *In re Hamisch*, 206 U.S.P.Q. 300 (CCPA 1980) and *Ex parte Dahlen and Zwilgmeyer*,42 U.S.P.Q. 208 (Bd. App., 1938), supports Applicants' position that the present restriction requirement is improper because, as stated above, the Action has concluded erroneously that the compounds of Applicants' claimed invention do not share a distinct structural feature linked to a particular function.

For example, in *In re Hamisch*, 206 U.S.P.Q. 300 (CCPA 1980), the court found that an invention claimed in a Markush type claim was proper for compounds having a common utility and "***a single structural similarity***" (emphasis added). In particular, in agreeing with its earlier decisions, the court stated that a Markush group was proper where there is a

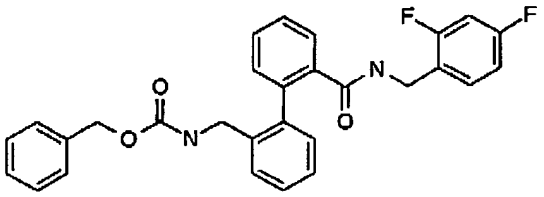
> grouping of compounds having the ***same nuclei but side chains wherein there was a wide variation*** ... and had ***a community of properties justifying their grouping*** ... was not repugnant to principles of scientific classification.

In re Harnisch, 206 U.S.P.Q. at 305 (emphasis added). The Court held that, when such criteria exist, there is unity of invention within the claimed Markush group. *Id.* Applicants' claimed invention meets the standard of *In re Harnisch* as it indeed has the requisite single structural similarity (*i.e.*, the substantial structural feature from MPEP §803.02) and shares a common utility, as noted above. Therefore, there is no propriety

for the present restriction/election and reconsideration and withdrawal of the election/restriction requirement are requested respectfully.

Provisional Election

Although Applicants submit respectfully that the imposed restriction requirement is improper, in an attempt to advance the prosecution of this application, Applicants provisionally elect **Group I** for prosecution along with the species **2'-(benzyloxycarbonylaminomethyl)biphenyl-2-carboxylic acid (2,4-difluorobenzyl)amide**



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which is the subject of **Example 6g** in the present patent application.

Applicants submit that once the compounds of the present invention are found to be novel, then the claims of Group IV should also be found to be novel and rejoined. Further, Applicants reserve the right to pursue any compounds that remain after prosecution of the instant patent application in a future divisional patent application.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Applicants respectfully submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. **18-1982** in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,

Dated: March 22, 2005

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Docket No. DEAV1999/L060 US NP2